PATENT APPLICATION
Attorney Docket No.: 285-183

NON-DESTRUCTIVE METHOD FOR EVALUATING CANCELLOUS BONE STRENGTH OF ALLOGRAFT TISSUE

CROSS-REFERENCE TO RELATED APPLICATION

The present application claims priority to U.S. provisional application Serial No. 60/243,170 filed October 25, 2000, the entire contents of which is hereby incorporated by reference.

BACKGROUND

1. Technical Field

This application is directed to a method for quickly and easily evaluating the strength of cancellous bone. More specifically, this application is directed to a non-destructive method for quickly and easily evaluating the strength of dense cancellous bone to determine the suitability of the cancellous bone for a particular surgical application.

2. Background of Related Art

The use of bone allografts in surgical procedures for repairing bone fractures, torn ligaments, spinal disorders, etc., is well known in the art. Examples of such allografts, designed specifically for use in spinal fusion procedures, are disclosed in U.S. provisional application serial Nos. 60/220,941, filed July 26, 2000, and 60/158,074, filed October 7, 1999. Both of these applications are incorporated herein by reference in their entirety.

The strength and quality of bone, particularly cancellous bone, varies greatly from donor to donor, and also from location to location within a single donor. For example, studies have shown that the apparent density of cancellous bone decreases significantly with age and that the apparent density of bone varies between genders. As the apparent density of bone decreases, the compressive strength, and thus the load bearing capacity, of the bone also decreases.

In a laboratory environment, the compressive strength of allograft bone can be determined using the appropriate machinery to subject the bone to a compressive force until failure occurs. Although the compressive strength of a particular specimen of cancellous bone can be determined using this method, this method is impracticable. Firstly, using this method, the particular specimen tested is destroyed. Secondly, the compressive strength of the specimen tested is not determinative of the compressive strength of cancellous bone from a different, or even the same donor.

As discussed above, cancellous bone allografts are used in a variety of surgical procedures including spinal fusion procedures, e.g., fusion procedures in the cervical region of the spine. In a spinal fusion procedure, at least a portion of the disc between adjacent vertebrae is removed and an allograft is positioned between adjacent vertebral endplates to retain and support the vertebrae at a fixed location with respect to each other. It is imperative to the success of such a procedure that the allograft be capable of withstanding the compressive forces generated by the vertebrae.

Accordingly, an improved method for determining the strength of allografts formed of cancellous bone is needed which does not destroy the bone and which can be easily and quickly performed by a technician.

SUMMARY

A non-destructive method for evaluating the strength of cancellous bone, includes the steps of performing at least two of the following test on each cancellous bone of a population of cancellous bones, namely, a manual compression test, an apparent density test, and an appearance test; determining a compressive strength for each cancellous bone based on the two tests performed; comparing the determined compressive strength of each cancellous bone against a predetermined compressive strength requirement; and eliminating a subset of cancellous bone from the population of cancellous bone, which subset of cancellous bone fails to meet the predetermined compressive strength requirement.

The manual compression test includes the steps of manually compressing each cancellous bone to make a subjective determination of the compressive strength of each cancellous bone and removing a cancellous bone from the population of cancellous bones when the manually compressed cancellous bone appreciably deforms. The appearance test includes the steps of assessing a quality of each cancellous bone based on their individual appearance and assigning each cancellous bone with a grade which designates a subjective quality assessment of each cancellous bone. The apparent density test includes the steps of cleaning each cancellous bone, freeze drying each cancellous bone, measuring the dimensions of each cancellous bone to determine a volume thereof, weighing each cancellous bone, determining an apparent density for each cancellous bone, and determining the compressive strength of each cancellous bone based on the apparent density.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Preferred embodiments of the presently disclosed non-destructive method for evaluating cancellous bone strength of allograft tissue will now be described.

The presently disclosed non-destructive method for evaluating cancellous bone strength of allograft tissue includes three separate tests which are performed by a technician during preparation of the allograft. These tests include the appearance test, the manual compression test and the apparent density test. Each test is used to determine or identify a subset of cancellous bone allografts which have better strength than those of the overall population of cancellous allografts.

Initially, a cancellous bone allograft is cut from cancellous bone of a donor into the desired configuration which may be a cylindrical dowel, a wedge, a rectangular spacer, etc. Prior to cutting, the donor bone may be cleaned using an external spray to remove soft tissue from the external surface of the bone. The allograft should be cut such that the first facing cuts (which will become the top or bottom loading surfaces of the allograft) are perpendicular to the trabecular orientation in the bone. Typically, these facing cuts will be perpendicular to the long axis of the bone. In this way, the graft will be loaded in a similar orientation to the loading orientation of the graft during the donor's lifetime as disclosed in the article "Orienting Cancellous Bone For The Preparation of Graftech Cervical Spacer" by Todd Boyce, the entire contents of which is hereby incorporated by reference. After the allograft has been cut into a desired configuration, a technician will perform each of the above-identified tests and evaluations.

The manual compression test may be performed prior to or after cleaning of the bone but

must be performed prior to freeze drying the allograft. In conducting the manual compression test, the cancellous bone allograft is compressed between the technician's fingers to make a subjective determination of the hardness and the compressive strength of the cancellous bone allograft. The manual compression test provides a first level of allograft screening. If the allograft compresses appreciably or deforms greatly between the fingers of a technician, the allograft is discarded. Discarded allograft bone can be used to form other osteoinductive materials or compounds. Using the manual compression test, trained technicians can consistently eliminate grafts which fall below a minimum required compressive strength. The minimum required compressive strength of the graft will vary according to the intended use of the graft, e.g., the minimum required compressive strength of a graft for use in the cervical spine is approximately 500 newtons.

After the manual compression test has been conducted and the cancellous bone allograft has been cleaned by removing the blood and marrow from the bone, the technician performs the appearance test. In conducting the appearance test, a technician assesses the quality of the allograft based on its appearance to determine if the allograft meets the standard of "dense cancellous bone". The technician will assign the load bearing allograft a rating using a Grade 1 to Grade 5 scale (1 being the most suitable for allograft use and 5 being the least suitable) to designate the technician's subjective quality assessment of the cancellous bone allograft. The attached description specifying in detail the characteristics of Grade 1 - Grade 5 allografts is disclosed in , "Freeze Dried Graftech Cervical Spacer: Implant Visual Grade Characteristics", the entire contents of which is hereby incorporated by reference. The appearance test can be conducted prior to or after freeze drying the bone.

Finally, an apparent density test of the cancellous bone allograft will be conducted to estimate the strength of the allograft. More specifically, each allograft is weighed and its dimensions are measured to determine the volume of the allograft (including the volume of the pore spaces). Knowing the weight and volume, the apparent density of the allograft can be easily determined. The apparent density test of each allograft should be conducted after the allograft has been cleaned, the cleaning solution has been removed from the allograft and the allograft has been freeze dried. Alternately, the apparent density test can be conducted prior to freeze drying the allograft. It is noted that if cancellous bone allografts are cut to specific dimensions, each allograft need not be measured independently but rather the volume of the allograft can be determined based on the pre-selected dimensions of the allograft. If the apparent density test is conducted prior to freeze drying, some process should be used to reduce the water content in the allograft bone to a predetermined level such that the volume of water remaining in the cancellous bone can be factored into the apparent density measurement. Using known data gotten through prior testing of a statistically significant number of cancellous bone samples, a graph can be plotted comparing compressive strength of cancellous bone v. apparent density of the cancellous bone. Using this graph, the compressive strength of a cancellous bone graft can be estimated after the apparent density of the graft has been determined. If the allograft has passed the manual compression test, the appearance test and has the required apparent density, the allograft is acceptable for allograft use.

It will be understood that various modifications may be made to the embodiments disclosed herein. For example, the order of the tests may be varied. Moreover, the degree to which the bone has been cleaned, freeze dried, or prepared before each or all of the tests are

conducted may vary, e.g., the cancellous bone need not be cleaned or it may undergo a complete cleaning cycle before conducting any one or all of the above-identified tests. Further, each of these tests may be used individually or in conjunction with any one or both of the remaining tests to eliminate unsuitable bone from consideration as graft bone. For example, the apparent density test may be used alone or in combination with only the manual compression test to identify a subset of cancellous bone allografts which meet or do not meet necessary strength requirements. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.